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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/572,591

12/14/2006

Elizabeth Wanda Murray

9369-354

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10/27/2010

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CANADA

EXAMINER

YU, HONG

ART UNIT

PAPER NUMBER

1613

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/572,591	<b>Applicant(s)</b> MURRAY ET AL.	
	<b>Examiner</b> HONG YU	<b>Art Unit</b> 1613	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 23-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 23-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's amendments and arguments filed 07/28/2010 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

#### ***Status of claims***

Claims 21 and 22 have been cancelled. Claims 1-20 and 23-34 are under examination in the instant office action.

#### **Rejections withdrawn**

Applicant's amendments have overcome objections from the previous Office Action.

#### **New ground of rejections necessitated by Applicant's amendment**

The limitation of "wherein the first solvent is an organic solvent selected from alcohols, aliphatic hydrocarbons, aromatic hydrocarbons, chlorinated hydrocarbons, glycols, glycol ethers and their acetates, esters, ethers and ketones" being brought from claims 21 and 22 into claim 1 and the omission of the limitation of "oil, lipid and fatty acid" from claim 22 when the limitation of claim 22 is brought to claim 1 necessitate the following new ground of rejections.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

***Claims 1-20, 25, and 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Deckers et al. (US 6,372,234 B1) as evidenced by Oil (retrieved on 10/23/2010, retrieved from the internet:***

***<URL:<http://www.geotech.org/survey/geotech/Oil.pdf>>).***

Deckers et al. meet all of the limitations of claim 1. Deckers et al. disclose a method of partitioning an active into oil bodies comprising dissolving active agent in oil to form oil phase, mixing aqueous phase with oil phase to form emulsion, and mixing emulsion with oil bodies (example 7). According to Oil oil comprises a variety of liquid hydrocarbon compounds (page 1, the paragraph under "What is oil?"). Liquid hydrocarbons inherently include aliphatic hydrocarbons and therefor the disclosure in Deckers et al. anticipates claim 1.

Deckers et al. meet all of the limitations of claims 2-4 and 20. Deckers et al. is silent about the active agent not being partitioned into oil bodies when contact with oil bodies in the absence of a solvent or when the active agent is dissolved in the first solvent alone, the active being insoluble in water, the active being insoluble in the second solvent, and first solvent being non-compatible with oil bodies or undesirable in the final product. The first solvent, the second solvent, the active agents, the oil bodies,

Art Unit: 1613

and the method of producing the composition comprising a first solvent, a second solvent, active agents, and oil bodies disclosed by Deckers et al. are the same as those recited in the instant claims, thus the active agent disclosed by Deckers et al. would necessarily possess the properties recited in the instant claims; not partition into oil bodies when contacted with oil bodies in the absence of a solvent or when the active agent is dissolved in the first solvent alone, the active agent being insoluble in water, the active being insoluble in the second solvent, and first solvent being non-compatible with oil bodies or undesirable in the final product.

Deckers et al. meet all of the limitations of claims 5-10. Deckers et al. is silent about 0.1% of an active agent being partitioned into oil bodies and the efficiency of partitioning of an active agent being 40%. The first solvent, the second solvent, the active agents, the oil bodies, and the method of producing the composition comprising a first solvent, a second solvent, active agents, and oil bodies disclosed by Deckers et al. are the same as those recited in the instant claims, thus the composition disclosed by Deckers et al. would necessarily possess the properties recited in the instant claims: having 0.1% of an active agent being partitioned into oil bodies and 40% partitioning efficiency of an active agent.

Deckers et al. meet all of the limitations of claims 11-19. Deckers et al. disclose clindamycin, retinoic acid, benzoyl peroxide, tetracaine, and lidocaine as active agents (column 20, line 19, 50, column 21, line 3, 4, and 28). Although Deckers et al. is silent about the active agent having a log P value of 3.5 and a HLB value of from about 1 to 14, from 4 to 10, and from 6 to 8; the active agents disclosed by Deckers et al. are as

Art Unit: 1613

same as the active agents recited in the instant claims, thus the active agents necessarily have a log P value of 3.5 and a HLB value of from about 1 to 14, from 4 to 10, and from 6 to 8.

Deckers et al. meet all of the limitations of claim 25. Deckers et al. disclose the the second solvent being water (example 7).

Deckers et al. meet all of the limitations of claims 31-34. Deckers et al. disclose the oil bodies in the composition are obtained from safflower (example 7).

Response to Applicants' arguments:

Applicant's arguments, filed on 07/28/2010, have been fully considered but they are moot in view of new ground of rejections. However the examiner would like to address the following arguments:

Applicants argue that the claimed system is more complexed than the system disclosed by Deckers et al. according to the disclosure on page 5, paragraph 36 and 38, in the instant specification.

However, this argument is not deemed persuasive. It is noted that the features upon which applicant relies (i.e., a step of incubation) is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Thus, Applicant's arguments are not commensurate in scope with the claims.

Art Unit: 1613

Applicants further argue that Deckers uses oil as the 2<sup>nd</sup> solvent while the claimed 2<sup>nd</sup> solvent is organic solvent such as aliphatic hydrocarbon.

However, this argument is not deemed persuasive. As stated in the 102 rejection above, according to Oil oil comprises a variety of liquid hydrocarbon compounds (page 1, the paragraph under "What is oil?").

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

***Claims 23, 24, 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deckers et al. (US 6,372,234 B1) as evidenced by Oil (retrieved***

Art Unit: 1613

**on 10/23/2010, retrieved from the internet:**

**<URL:<http://www.geotech.org/survey/geotech/Oil.pdf>>) in view of Gregoriadis**

**(“Liposome Technology, Volume II, Incorporation of Drugs, Proteins, and Genetic Material”, CRC Press, Inc., Boca Raton, Florida, 1983. p29) and Desai et al. (US 5,916,596).**

### ***Applicant's claims***

Applicants recite a method of partitioning an active agent into oil bodies comprising dissolving an active agent in a first solvent; mixing the dissolved active agent with a second solvent to obtain a mixture of the active agent, first solvent, and second solvent; contacting the said mixture with oil bodies to partition the said active agent into the said oil bodies with chloroform as the first solvent and monobasic sodium phosphate and safflower oil, respectively, as the second solvent (see claims 23, 24, 26, and 27).

Claims 28 and 29 recite the first solvent is substantially removed after it has been mixed with the second solvent by evaporation.

### ***Determination of the Scope and Content of the Prior Art***

#### ***(MPEP 2141.01)***

The teachings of Deckers et al. and Oil are discussed above and applied in the same manner.

### ***Ascertainment of the Difference between Scope of the Prior Art and the Claims***

#### ***MPEP 2141.02)***



Deckers et al. do not teach: i) chloroform being the first solvent and monobasic sodium phosphate being the second solvent; ii) removing the first solvent by evaporation after the first solvent has been mixed with the second solvent.

These deficiencies are cured by Gregoriadis and Desai. Gregoriadis teaches a method of preparing a poorly soluble drug entrapped in a lipid solution wherein the drug is dissolved in dimethyl sulfoxide as a first solvent and mixed with 10% phosphate buffer saline. The mixture is then contacted with a lipid mixture and the first solvent is removed by rotary evaporation (example D/1). Desai et al. teach both chloroform and dimethyl sulfoxide can be used as a solvent to dissolve a pharmaceutically active agent (column 9, line 1-6).

***Finding of Prima Facie Obviousness Rational and Motivation***  
***(MPEP 2142-2143)***

It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Deckers et al., Gregoriadis, and Desai et al. to choose chloroform as the first solvent and monobasic sodium phosphate as the second solvent. Using dimethyl sulfoxide as a first solvent and 10% phosphate buffer saline as a second solvent and both chloroform and dimethyl sulfoxide being used as solvent to dissolve a pharmaceutically active agent were well known to a person of ordinary skill in the art at the time of the invention. The motivation for choosing chloroform as the first solvent and monobasic sodium phosphate as the second solvent flows from their having been used in the prior art, and from their being recognized in the prior art as useful for the same purpose. As shown by the recited

Art Unit: 1613

teachings, the instant claims are no more than choosing two conventional solvents to form an emulsion.

It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Deckers et al. and Gregoriadis to choose to add a step of removing one of the two solvents in an emulsion before contacting with a lipid mixture. The “oil bodies” is define as any subcellular oil or wax storage organelle in the disclosure of the instant specification (page 7, line 5-7), thus the “oil bodies” is one of lipid mixtures. Adding a step of removing one of the two solvents in an emulsion before contacting with a lipid mixture was well known to a person of ordinary skill in the art at the time of the invention. The motivation for adding it flows from its having been used in the prior art, and from its being recognized in the prior art as useful for the same purpose. As shown by the recited teachings, instant claims are no more than adding a conventional step in the formation of a composition with poorly water-soluble active agent. It therefore follows that the instant claims define prima facie obvious subject matter.

***Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Deckers et al. (US 6,372,234 B1) as evidenced by Oil (retrieved on 10/23/2010, retrieved from the internet: <URL:<http://www.geotech.org/survey/geotech/Oil.pdf>>) and Gregoriadis (“Liposome Technology, Volume II, Incorporation of Drugs, Proteins, and Genetic***

Art Unit: 1613

***Material”, CRC Press, Inc., Boca Raton, Florida, 1983. p29), and further in view of Kaufman et al. (US 5,616,330).***

***Applicant’s claims***

Applicants claim that the first solvent is evaporated by exposing to a stream of nitrogen (see claim 30).

***Determination of the Scope and Content of the Prior Art***

***(MPEP 2141.01)***

The teachings of Deckers et al., Oil, and Gregoriadis are discussed above and applied in the same manner.

***Ascertainment of the Difference between Scope of the Prior Art and the Claims***

***MPEP 2141.02)***

Deckers et al. and Gregoriadis do not specify the first solvent is evaporated by exposing to a stream of nitrogen.

This deficiency is cured by Kaufman et al. who teach rotary evaporation of a solvent or evaporation of a solvent under a stream of nitrogen (column 4, line 30-33).

***Finding of Prima Facie Obviousness Rational and Motivation***

***(MPEP 2142-2143)***

It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Gregoridis and Kaufman et al. to remove the first solvent by exposing to a stream of nitrogen. Removing a solvent with rotary evaporation or removing a solvent with evaporation under a stream of nitrogen were well known methods of removing solvent to a person of ordinary skill in the art at

Art Unit: 1613

the time of the invention. It is generally considered to be prima facie obvious to remove a solvent with evaporation under a stream of nitrogen based on the chemical and physical properties of the first solvent, the second solvent, and the active agent. As shown by the recited teachings, the instant claims are no more than choosing a conventional evaporation method.

Response to Applicants' arguments:

Applicant's arguments, filed on 07/28/2010, have been fully considered but they are moot in view of new ground of rejections. However the examiner would like to address the following arguments:

Argument regarding the 103 rejection is basically the same as the above 102 rejection, thus the response discussed above applies here as well and is not persuasive for reason discussed above.

Applicants argue that the inventor have demonstrated the novel method leads to an improvement in the partitioning of active agents into oil bodies and Deckers et al. do not teach a novel method for partitioning active agents into oil bodies.

However, this argument is not deemed persuasive. First of all, there is no experiment result of side-by-side comparison with the closest to prior art to demonstrate the improvement. Secondly, although Deckers do not teach a novel method for partitioning active agents into oil bodies, partitioning active agents into oil bodies would necessarily happen with the method taught by Deckers et al., whether Deckers et al.

Art Unit: 1613

realize it or not. Respectfully, applicants' arguments are not persuasive. The predictable and expected result remains predictable and expected. Accordingly, the claims remain rejected for at least these reasons and the reasons of record.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brain-Yong Kwon can be reached on 571-272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1613

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. Y./  
Examiner, Art Unit 1613

/Ernst V Arnold/  
Primary Examiner, Art Unit 1613